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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,631	03/01/2002	Stephan Jaeger	1803-335-999	3750
20583	7590	07/30/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				WILDER, CYNTHIA B
		ART UNIT		PAPER NUMBER
		1637		

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/087,631	JAEGER, STEPHAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 June 2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 9-14 and 20-33 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 9-14 and 20-33 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 6/1/2004.

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2004 has been entered. Claims 1-8 and 15-19 have been canceled. Claims 20-33 have been added. Claims 9-24 and 2-33 are pending and discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Previous Rejections***

2. The prior art rejection under 35 USC 102(b) directed to claims 6-12 as being anticipated by Mullis et al is withdrawn in view of the new grounds of rejections discussed below. The prior art rejection under 35 USC 102(b) directed to claims 6, 8, 9 and 11 as being anticipated by Nadeau is maintained is withdrawn in view of the new grounds of rejections discussed below. The prior art rejection under 35 USC 102(b) directed to claims 6, 7, 9, 10 and 12-14 as being anticipated by Tsang et al is withdrawn in view of the new grounds of rejections discussed below. The prior art rejection under 35 USC 102(b) directed to claims 15-19 is withdrawn in view of Applicant's cancellation of the claims. The new matter rejection directed to the

specification under 35 USC 112 first paragraph is withdrawn in view of Applicant's amendment to the specification.

***New Ground(s) of Rejections***

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 9-12, 21, 22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Gagnor et al (Nucleic acids Research, Vol. 17, No13, pages 5701-5114). Regarding claims 9 and 22, Gagnor et al teach a composition comprising a target nucleic acid and a control nucleic acid (ps-β-I and ps-α-II), wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 (clm 9) or at least 10 (clm 22) nucleotides in length essentially parallel complementary to said target nucleic acid region (see Figure 1, page 5108 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claims 10-12, Gagnor et al teach the composition of claim 9, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claim 21, Gagnor et al teach the composition of claim 9, wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claim 24 and 25, Gagnor et al teach the composition of claim 10, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108). Therefore, Gagnor et al meets the limitations of claims 9-12, 21, 24 and 25 of the instant invention.

5. Claims 9 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolli et al (Nucleic acids Research, Vol. 24, No. 23, pages 4665-4672). Regarding claims 9 and 20, Bolli et al teach a composition comprising a target nucleic acid and a control nucleic acid, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region or to the complementary strand of said target nucleic acid region. Bolli et al further teach wherein said target nucleic acid is DNA. (see page Table 2 at C). Therefore, Bolli et al meets the limitations of claims 9 and 20 of the instant invention.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13, 14, 27, 28, 30, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gagnor et al as previously applied above in view of Ahern, H. The Scientist, vol. 9, No. 15, pages 20-24, July 1995). Regarding claims 13 and 28, Gagnor et al teach a composition comprising a target nucleic acid and a control nucleic acid (ps- $\beta$ -I and ps- $\alpha$ -II), wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 (clm 13) or at least 10 (clm 28) nucleotides in length essentially parallel complementary to said target nucleic acid region (see Figure 1, page 5108 and page 5110, first paragraph, under "Results", lines 1-10). Gagnor et al differs from the instant invention in that the reference does not expressly teach the composition in the form of kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-forth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have combined the composition as taught by Gagnor et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

Regarding claims 14, 30, 32 Gagnor et al teach the composition of claim 13, wherein said target nucleic acid comprises a primer binding site or a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the primer binding site or probe binding site of the target nucleic acid (Figure 1, page 5108; page 5110, first paragraph, under "Results", lines 1-10 and page 5112, lines 3-7).

Regarding claim 27, Gagnor et al teach the composition of claim 13 wherein the target nucleic acid is an RNA molecule (Figure 1 and page 5110, first paragraph, under "Results", lines 1-10).

Regarding claim 31 and 33, Gagnor et al teach the composition of claim 13, further comprising a primer or probe (aps-β-I and aps-α-II) that binds to the primer-binding site or the probe-binding site (Figure 1, page 5108).

8. Claims 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolli et al. as previously applied above in view of Ahern, H (The Scientist, Vol. 9, No. 15, pages 20-24, July 1995). Regarding claims 13 and 26, Bolli et al teach a composition comprising a target nucleic acid and a control nucleic acid, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region or to the complementary strand of said target nucleic acid region. Bolli et al further teach wherein said target nucleic acid is DNA (page Table 2 at C). Bolli et al differ from the instant invention in that the reference does not teach the composition in the form of a kit.

In a scientific article, Ahern teaches the advantages of a kit and provides motivation for combining reagents in the form of a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 23, second-forth paragraphs). Therefore, in view of the teaching of Ahern, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have combined the composition as taught by Bolli et al in the form of a kit for the obvious benefits of convenience, time management and ease of practicing to the investigator as suggested by Ahern.

***Prior Art***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gagnor et al. (Nucleic acids Research, Vol. 15, No. 24, pages 10419-10436) teach a composition comprising a target nucleic acid and a control nucleic acid, wherein said control nucleic acid comprises at least 8 or more contiguous nucleotides that is essentially parallel complementary to a target nucleic acid region (see page 10424, Figure 1).

***Conclusion***

10. Claims 9-14, 20-22, 24-28 and 30-33 are rejected. Claims 23 and 29 have not been rejected under prior art but are objected to because they depend from a rejected claim. No prior art was found wherein the composition further comprise a thermostable polymerase. No motivation could be found in the prior art for combining a thermostable polymerase with the composition as claimed. Accordingly an obviousness-type rejection could not be made against the claims 23 and 29 of the instant invention. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

**FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
CYNTHIA WILDER  
PATENT EXAMINER  
